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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.            | CONFIRMATION NO.       |
|---|-------------|----------------------|--------------------------------|------------------------|
| 10/518,966  | 11/04/2005  | Jolanta Gutkowska    | 29105/40749                    | 8084                   |
| 4743 7590 12/27/2007<br>MARSHALL, GERSTEIN & BORUN LLP<br>233 S. WACKER DRIVE, SUITE 6300<br>SEARS TOWER<br>CHICAGO, IL 60606 |             |                      |                                |                        |
|   |             |                      | EXAMINER<br>NIEBAUER, RONALD T |                        |
|   |             |                      | ART UNIT<br>1654               | PAPER NUMBER           |
|   |             |                      | MAIL DATE<br>12/27/2007        | DELIVERY MODE<br>PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/518,966

Applicant(s)

GUTKOWSKA ET AL.

Examiner

Ronald T. Niebauer

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1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 25 May 2005.
- 2a) ☐ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-41, 66, 67 and 69 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-41, 66, 67, 69 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

Claims 42-65,68 have been cancelled.

Claims 1-41,66-67,69 are under consideration.

#### *Election/Restrictions*

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

**Group 1, claim(s) 3 in part, 4, 15 in part, 16, 29 in part, 30**, drawn to a method of inducing/treating using oxytocin or a functional derivative thereof.

**Group 2, claim(s) 3 in part, 15 in part, 29 in part**, drawn to a method of inducing/treating using retinoic acid.

**Group 3, claim(s) 3 in part, 15 in part, 29 in part**, drawn to a method of inducing/treating using triiodothyronine.

**Group 4, claim(s) 5, 6, 17, 18, 31, 32**, drawn to a method of inducing/treating using a nucleic acid.

**Group 5, claim(s) 66-67,69** drawn to a method of identification.

Claims 1-2, 7-14, 19-28, 33-41 drawn to a method of induction/treatment, link(s) inventions 1-4. The restriction requirement between the linked inventions is **subject to the** nonallowance of the linking claim(s), Claims 1-2, 7-14, 19-28, 33-41. The restriction

requirement between the linked inventions is **subject to** the nonallowance of the linking claim(s), Claims 1-2, 7-14, 19-28, 33-41. Please note, the linking claims do not link the inventive groups of group 5.

Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions **shall** be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104 **Claims that require all the limitations of an allowable linking claim** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, the allowable linking claim, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The inventions listed as Groups 1-5 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: PCT Rule 13.2 defines "special technical features" as "those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art." Claim 1 is drawn to a method of inducing

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differentiation of a non-cardiomyocyte into a cardiomyocyte. Rodriguez et al. (as cited in IDS) teach a method of inducing cardiac differentiation in P19 cells by treating them with triiodo-L-thyronine (abstract). Since Rodriguez teach a method of contacting non-cardiomyocytes with triiodo-L-thyronine (compare claim 3 of the current invention) the technical feature is not a contribution over the prior art and the claims lack unity. It is noted that Rodriguez does not expressly report oxytocin receptor activity. Since the active steps are the same and the product meets the structural limitations, the properties/functions applicant discloses are necessarily present and thus the technical feature is not a contribution over the prior art and the claims lack unity.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

### *Election/Restrictions*

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

If Group 1 is elected:

**Oxytocin or functional derivative:** a single species such that all variable groups are uniquely defined should be identified (compare claim 4,16,30).

If Group 4 is elected:

**Nucleic acid:** a single species such that all variable groups are uniquely defined should be identified (compare claim 6,18,32).

**Further, if any of group 1-4 is elected:**

**Non-cardiomyocyte type:** a single type should be identified (compare claims 7-9, 19-21, 33-35).

**Phenotypic feature:** a single feature should be identified (compare claims 12, 41).

**Disease:** a single disease should be identified (compare claim 23).

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

Claims 1-2, 7-14, 19-28, 33-41 are generic.

There is an examination and search burden for the species due to their mutually exclusive characteristics. Each of the species are structurally distinct and one of skill in the art would not recognize that every alternative would behave in the same way. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing

different search queries); and/or the prior art applicable to one species would not likely be applicable to another species.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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*Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ronald T. Niebauer whose telephone number is 571-270-3059. The examiner can normally be reached on Monday-Thursday, 7:30am-5:00pm, alt. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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ANISH GUPTA  
PRIMARY EXAMINER